

MAR 7 - 2005

**510(k) Summary
DIVER™ C.E. Catheter**

510(k) Number: K050276

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter/Contact Person:

Applicant
(Manufacturer):

Invatec Innovative Technologies
Via Martiri della Libertà, 7
25030 Roncadelle (BS) Italy
Tel: +39 030 258 93 11
Fax: +39 030 258 93 12

Submitter's Name:

ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442
Tel: (763) 398-7000
Fax: (763) 398-7200

Official Contact:

Patrice Stromberg
Sr. Regulatory Affairs Specialist
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442
Tel: (763) 398-7487
Fax: (763) 398-7200
pstromberg@ev3.net

Summary Preparation Date:

February 4, 2005

Device Name and Classification:

Trade Name:
Common Name/Usual Name:
Classification Name:
Class:

DIVER™ C.E. Catheter
Catheter, Embolectomy
Catheter, Embolectomy
Class II, 21 CFR 870.5150

Predicate Devices:

Vascular Solutions Pronto™ Extraction Catheter (K032763)
Invatec Innovative Technologies SUBMARINE PLUS™ PTA Catheter
(K042537)
Invatec Innovative Technologies AMPHIRION DEEP PTA Balloon Catheter
(K042624)

Device Description:

The DIVER C.E. Catheters are aspiration catheters indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. The catheters feature an aspiration lumen running through the full length of the catheter. A luer lock type hub in the proximal end allows the connection of a stopcock and a syringe for blood aspiration and clot removal (not provided). The DIVER C.E. Catheters have a central aspiration lumen and a soft, atraumatic tip. The smooth, soft, atraumatic tip has a radiopaque marker band located at 1mm from its distal end. The DIVER C.E. Catheters are available in two configurations, with and without sideholes. The catheters are a rapid exchange design, with the guide wire lumen running from the distal tip to 22.7 cm proximally in the catheter body, where the exit port is located. The catheters are compatible with guide wires with a maximum diameter of 0.014”.

Intended Use:

The DIVER C.E. Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Summary of Testing:

Biocompatibility. Biocompatibility testing in accordance with ISO 10993, "Biological Evaluation of Medical Devices," 1997(E) and FDA Memorandum #G95-1, "Biological Evaluation of Medical Devices" was provided. The material used in the Invatec DIVER C.E. Catheter has been demonstrated to be biocompatible.

Performance Data: Comparison bench tests regarding performance characteristics were performed on the DIVER C.E. Catheter (with sideholes), DIVER C.E. Catheter (without sideholes), and the predicate devices to demonstrate equivalency.

Statement of Equivalence:

The DIVER C.E. Catheters are substantially equivalent to the currently marketed Vascular Solutions Pronto™ Extraction Catheter (K032763), Invatec SUBMARINE PLUS™ PTA Catheter (K042537) and Invatec AMPHIRION DEEP™ PTA Balloon Catheter (K042624) in intended use, performance, technological characteristics and materials.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 7 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ev3 Inc.
c/o Mr. Patrice Stromberg
Sr. Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, MN 55442-2920

Re: K050276
Diver C.E. Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: February 4, 2005
Received: February 7, 2005

Dear Mr. Stromberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

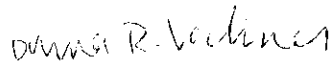
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Patrice Stromberg

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K050276

Device Name: DIVER™ C.E. Catheter

Indications for Use:

The DIVER C.E. Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Daniel R. Volante
(Division Sign-Off)
Division of Cardiovascular Devices

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